

**IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF MASSACHUSETTS**

DEAN LANGFORD and  
NANCY LANGFORD,  
husband and wife,

Case No.: 03-12245-RCL

Plaintiffs,

v.

ZIMMER, INC. and  
ZIMMER HOLDINGS, INC.,

Defendants.

**MEMORANDUM IN SUPPORT OF MOTION TO STRIKE**

Zimmer, Inc. and Zimmer Holdings, Inc. ("Zimmer"), by their attorneys, respectfully submit this memorandum in support of their motion to strike.<sup>1</sup>

**I.**  
**INTRODUCTION**

This action is a medical device product liability lawsuit arising out of an April 1992 surgery in which Plaintiff Dean Langford ("Plaintiff") underwent surgery to replace his left hip. Plaintiff's surgeon allegedly used a cemented femoral component manufactured and sold by Zimmer, a Centralign femoral stem ("Centralign"). On or about November 13, 2003, Plaintiff and his spouse ("Plaintiffs") filed an action against Zimmer in which they allege that the Centralign is defective and unreasonably dangerous. Plaintiffs' complaint is not a short and plain statement of the claim; it is not simple, concise, and direct; and it contains redundant, immaterial, and impertinent allegations. For the reasons set forth below, the Court should strike certain allegations, which fall into three principal categories: 1) irrelevant and

<sup>1</sup> As certified in the attached motion, Zimmer's counsel drafted a letter to Plaintiffs' counsel setting forth its objections to Plaintiffs' complaint as prescribed by Local Rule 7.1(a)(2). The parties were unable to resolve the issue despite this good faith attempt.

prejudicial allegations relating to Zimmer's alleged corporate "vision," "mission," and "values;" 2) verbose, immaterial and pejorative allegations about products not at issue in this litigation (some of which currently are being sold); and 3) impertinent allegations regarding Zimmer's sales figures.

## II. STATEMENT OF FACTS

Plaintiffs' complaint includes the following allegations:

9. At all relevant times, Zimmer has held itself out to the public as a leader in orthopaedic knowledge. According to its own public statements, Zimmer's "vision" is "to be the global leader in enhanced quality of life for orthopaedic patients. To place confidence in the surgeons' skilled hands. To reaffirm our traditions, inspire our future and ensure our success through each patient's new freedom." Zimmer's "mission" is "to develop, produce and globally market the highest quality orthopaedic product and services that repair, replace and regenerate. Through the hands of skilled surgeons, we will enhance patient quality of life." Zimmer's stated "values" include a "pledge to quality" holding that "[p]atients trust that our life's work will safely and effectively improve their lives. We are committed to defect-free products." Zimmer's public representation is that "[t]he Zimmer brand represents excellence in our industry and the highest-quality products and services."

\* \* \*

17. Zimmer manufactured and marketed roughened hip stems pre-coated with PMMA from 1986 through the present. A family of products was produced including Iowa Grit-Blasted, Harris Precoat, Precoat Plus, Centralign, and VerSys-Plus. Only the VerSys-Plus remains in production.

18. On information and belief, Zimmer was the only manufacturer to roughen and PMMA precoat its stems.

19. Each of these femoral stems, Iowa Grit-Blasted, Harris Precoat, Precoat Plus, Centralign, and VerSys Plus, performed poorly. Each of these femoral stems has been the subject of peer reviewed journal articles that objectively demonstrated substandard performance. Respected orthopedic surgeons called for the abandonment of each of these femoral stems (including some of the physicians who participated in their design).

20. With regard to the Iowa Grit-Blasted stem, for example, one of its creators wrote in a leading orthopaedic journal:

The use of femoral components with a matte finish, and more dramatically with a grit blasted surface finish, produced more osteolysis and significantly more femoral revisions when compared with the polished Charnley femoral component in the younger patient population. (The primary author has returned to using a polished surface finish of the femoral component based on these observations...)

Callaghan, Johnston, and Pedersen, *The John Charnley Award: Practice Surveillance: A practical method to assess outcome and to perform clinical research*. Clinical Orthopaedics & Related Research, 369: 25-28 (1999).

21. With regard to the Harris Precoat and Precoat Plus, another group of authors noted:

The rate of failure of a modern precoated femoral components was found to be higher than one would have anticipated and stands in marked contrast to the failure rate of an older prosthesis with nearly twice the duration of follow-up. The causes of failure are multifactorial, but it would appear that an important element in the present series was the design and surface treatment of the femoral component, including the increased surface roughness and precoating with methylmethacrylate.

Ong, Wong, Lai, Garino and Steinberg, *Early Failure of Precoated Femoral Components in Primary Total Hip Arthroplasty*, Journal of Bone and Joint Surgery, 84(5):786-792 (2002).

22. With regard to the VerSys Plus, one author has written that its precoated components "have revealed higher than expected early loosening rates" despite design modifications such as stem length, geometry, and surface finish. The author reviewed 72 Zimmer VerSys Plus precoated femoral components implanted during 1997-1998 by two surgeons. At 3-4 year follow-up, the incidence of aseptic loosening necessitating revision surgery was 11% (nine patients). Osteolysis was severe and progressing rapidly and "three hips developed pathologic subtrochanteric stress fractures as a result of loosening and osteolysis." According to the author, "[w]hen loosening develops, the extent of osteolysis is more dramatic than what is normally seen around loose hip implants." The author does not advocate the use of PMMA precoated femoral components for THA. K.A. Fizzet, *Unacceptable failure with a currently available PMMA-precoated femoral component in total hip arthroplasty (Zimmer VerSys-Plus)*, Abstract from the Association of Hip and Knee Surgeons (Nov. 2001).

23. The Iowa Grit-Blasted, Harris Precoat, and Precoat Plus stems mode of failure often involved debonding, or separation, of the interface between the precoat cement (grout) and the metal femoral stem. Wear debris consisting of tiny particles of bone cement and polyethylene or metal from the implant articulating surfaces enter the gap created by the debonding and then elicit a response from debris scavenger cells (phagocytes). Thus activated, these cells then secrete substances that activate bone-consuming cells (osteoclasts). Local bone loss (osteolysis) is the end result of this biologic process that begins when the number of wear particles generated in the joint space overwhelms the capsule's capacity to clear them. The loss of bone often results in implant loosening. The loose (unstable) implant then often becomes painful and must be removed and replaced surgically. Compared to successful primary hip replacement, this "revision surgery" is more difficult to achieve and sometimes produces a less satisfactory result. (This mode of failure is the same with regard to the VerSys Plus.)

24. The problem of debonding and osteolysis was well known to Zimmer as was the poor performance of the Iowa Grit-Blasted, Harris Precoat, and Precoat Plus stems. Zimmer stopped producing and marketing them.

\* \* \*

28. Using the representations enumerated above, along with others, Zimmer aggressively marketed the Centralign Precoat Hip Prosthesis. According to an authoritative industry source, sales of the Centralign Precoat Hip Prosthesis have exceeded \$122 million and have been, on a yearly basis, as follows:

	<u>Units (each)</u>	<u>\$ (millions)</u>
1993	13,397	25.7
1994	13,886	24.1
1995	12,883	21.7
1996	15,166	23.5
1997	9,732	15.1
1998	2,295	4.0
1999	2,728	7.3
2000 (Jan-Jun)	<u>351</u>	<u>0.9</u>
<b>Total</b>	<b>70,438</b>	<b>\$122.3</b>

Source: IMS America, Hospital Supply Index

[Plaintiffs' Complaint at ¶¶ 9, 17-24, 28.]

### **III. ARGUMENT**

As shown below, settled federal pleading principles compel the conclusion that Plaintiffs' allegations are not proper. Fed. R. Civ. P. 12(f) states that "[u]pon motion made by a party before responding to a pleading...or upon the court's own initiative at any time, the court may order stricken from any pleading any insufficient defense or any redundant, immaterial, impertinent, or scandalous matter." Fed. R. Civ. P. 8(a)(2) requires that the complaint contain "a short and plain statement of the claim showing that the pleader is entitled to relief." Fed. R. Civ. P. 8(e)(1) provides that "[e]ach averment of a pleading shall be simple, concise, and direct."

The principles behind Rule 12(f) are well-recognized within the First Circuit. Motions to strike brought pursuant to Rule 12(f) "at an early stage of a complicated lawsuit may be extremely valuable to all concerned 'in order to avoid the needless expenditures of time and money,' in litigating issues which can be foreseen to have no bearing on the outcome." *Narragansett Tribe of Indians v. Southern Rhode*

*Island Land Dev. Corp.*, 418 F. Supp. 798, 801 (D.R.I. 1976). Courts must strike redundant, immaterial, impertinent, or scandalous matters because “they are superfluous descriptions and not substantive elements of the cause of action.” *Alvarado-Morales v. Digital Equip. Corp.*, 843 F.2d 613, 618 (1st Cir. 1987). “Immaterial” allegations are those that have “no essential or important relationship to the claim for relieve or the defenses being pleaded.” 5A Wright & Miller, Fed. Prac. & Proc. Civ.2d § 1382 (1993). *See, Automatic Radio Mfg. Co. v. National Carbon Co.*, 35 F. Supp. 454, 455 (D. Mass 1940) (allegations immaterial to cause of action must be stricken). “Impertinent” matter consists of “statements that do not pertain, and are not necessary, to the issues in question. Thus, there is considerable overlap between the concepts of ‘impertinent’ and ‘immaterial’ matter.” Wright & Miller, § 1382, *supra*. *See, Mulloney v. Federal Reserve Bank of Boston*, 1 F.R.D. 153, 155 (D. Mass 1940) (allegations of events predating the alleged conspiracy at issue were clearly irrelevant, overly prejudicial and properly stricken).

*In re Agent Orange Product Liability Litigation*, 475 F. Supp. 928 (E.D.N.Y. 1979) is instructive. In this products liability case, the plaintiff included 425 paragraphs of allegations regarding the corporate history of the defendants. *Id.* at 936. The court ordered all references to the corporate history stricken pursuant to Rule 12(f) because “these allegations are unnecessary, would be burdensome to answer, and would unduly prejudice defendants, the court in its discretion strikes all allegations relating to the corporate history of the defendants.” *Id.*

Similarly, the First Circuit enforces the public policy supporting Rule 8 as articulated by the Supreme Court. The purpose of Rule 8 is to codify the principles of simple notice pleading used in federal courts. Courts therefore expect the complaint to set forth only enough facts to give the defendant “fair notice of what the plaintiff’s claim is and the grounds upon which it rests.” *Conley v. Gibson*, 355 U.S. 41, 47, 78 S. Ct. 99,103 (1957). District courts throughout the First Circuit courts use Rule 8 as a basis to strike pleadings or allegations that do not conform to the “short and plain statement” requirement of Rule 8(a)(2) and the “simple, concise and direct” constraint of Rule 8(e)(1). *See Greenwood v. Orr & Sembower, Inc.*, 158 F. Supp. 906, 908 (D. Mass. 1958) (“lengthy statements which include evidentiary details” must be stricken); *Michelson v. Shell Union Oil Corp.*, 26 F. Supp. 594, 595 (D. Mass. 1939)

(allegations stricken for failure to complaint with Rule 8(a) requirement of a short and plain statement of the claim).

Presented with a complaint that “fails to set forth concisely...the substantive facts relied upon as constituting [plaintiff’s] alleged cause of action,” a Massachusetts district court determined that the complaint “failed to comply with the provisions” of Rule 8 and must be stricken. *Scalese v. City of Haverhill*, 198 F. Supp. 431, 432 (D. Mass. 1961).

Similarly, in *Martin v. Hunt*, 28 F.R.D. 35 (D. Mass. 1961), the district court dismissed a complaint composed of “a prolix and verbose series of allegations” due to its failure to comply with Rule 8’s requirement of “a short and plain statement of claim showing entitlement to relief.” *Id.* at 35. In its analysis, the court noted:

A large portion of the complaint consists of the setting forth in detail of matters of an evidentiary nature. The complaint is argumentative, redundant and verbose, and contains certain material which is both impertinent and scandalous.

\* \* \*

The complaint herein totally fails to comply with either the letter or the spirit of Rule 8(a) or Rule 8(e)(1) which requires each averment of a pleading to be simple, concise, and direct, and it is the complete antithesis of the type of complaint contemplated by Rule 8(a)(2)...

*Id.* at 35-36.

Additional guidance comes from the Ninth Circuit. In *McHenry v. Renne*, 84 F.3d 1172 (9th Cir. 1996), the Ninth Circuit upheld a district court’s striking a complaint pursuant to Rule 41(b) (which provides for involuntary dismissal upon failure of plaintiff to comply with court order) when the plaintiff’s second and third amended complaints defied the court’s orders to edit its complaint to comply with Rule 8’s “short and plain” requirements. The court, quoting from the district court’s order to strike the complaint, noted that the complaint’s contents were “mostly, ‘narrative ramblings’ and ‘storytelling or political griping.’” *Id.* at 1176. The *McHenry* court identified the complaint’s numerous faults to include:

[T]he complaint in the case at bar is argumentative, prolix, replete with redundancy, and largely irrelevant. It consists largely of immaterial background information. For example, the complaint explains that plaintiff McHenry cofounded his political organization in Cambridge, Massachusetts in 1980, which is irrelevant. It explains that McHenry's organization adheres to "the principles of non-violence developed by Gandhi and King," also irrelevant. It tells what brand of motorbikes the police officers who arrested people rode, and points out that a journalist was injured by a police officer at one of the mass arrests at Food Not Bombs distributions. It describes in detail settlement negotiations which Food Not Bombs had at various times and in various other law suits, telling what a United States district judge told the City he was considering in a settlement conference in another lawsuit. It accuses persons other than the defendants of having "falsely told members of the press" about an injunction. The complaint says, and illustrates with a dramatic illustration of the mayor rising from his desk chair, that Mayor Agnos seemed quite angry when he met with McHenry.

....

... Rather than set out the basis for a lawsuit, the pleading seems designed to provide quotations for newspaper stories.

*Id.* at 1177-78.

Finally, the *McHenry* court identified the public policy considerations supporting the dismissal of certain pleadings pursuant to Rule 8, stating that "[p]rolix, confusing complaints such as the ones plaintiffs filed in this case impose unfair burdens on litigants and judges... '[T]he rights of the defendants to be free from costly and harassing litigation must be considered.'" 84 F.3d at 1179-80, *quoting Von Poppenheim v. Portland Boxing & Wrestling Comm'n*, 442 F.2d 1047, 1054 (9th Cir. 1971).

**A. Plaintiffs' Impertinent Allegations of Zimmer's "Vision," "Mission," and "Values" Must Be Stricken**

Plaintiffs' claims are based on the following theories: 1) negligent development, design, manufacture, production, testing, labeling, marketing, advertising, sale, promotion, and/or distribution of the Centralign; 2) strict liability for failure to warn; 3) strict liability for defective design, manufacture and testing; 4) breach of express warranties; 5) breach of implied warranties; and 6) loss of consortium. Zimmer's vision, mission and values are irrelevant to the Plaintiffs' burden of proof with respect to these claims. Paragraph 9 of Plaintiffs' complaint contains nothing but a pejorative parsing of what Plaintiffs' alleges to be public statements by Zimmer about those subjects. "[T]hese allegations are unnecessary,

would be burdensome to answer, and would unduly prejudice defendants” and are therefore properly stricken pursuant to Rule 12(f). *In re Agent Orange Product Liability Litigation*, 475 F. Supp. at 936. The provisions of Rule 8 similarly require striking the allegations. Rather than providing a simple, concise and direct statement of the claims, the paragraph “seems designed to provide quotations for newspaper stories” and the allegation is properly stricken. *McHenry*, 84 F.3d at 1177-78.

**B. Plaintiffs’ Immaterial Allegations Regarding Products Not At Issue in the Instant Litigation Must Be Stricken**

Plaintiffs’ claims and alleged bases for recovery relate solely to the implant alleged to have been received by Plaintiff: a Centralign. In several paragraphs, however, Plaintiffs make allegations about products other than the Centralign. One of the products, the VerSys, is on the market today. Immaterial allegations about products being sold today have only one purpose—to prejudice Zimmer’s relationship with its customers and in the marketplace. In addition, each of the other products mentioned in the complaint has been implanted in thousands of patients, leading to the conclusion that the immaterial allegations also are intended to foment litigation. Allegations regarding Zimmer products other than the Centralign implant at issue in the instant litigation are immaterial, unduly prejudicial, and likely not admissible. The assertions in paragraphs 17 – 24 of Plaintiffs’ complaint must be stricken pursuant to Rule 12(f). *See U.S. ex rel. Alasker v. Centracare Health System, Inc.*, No. Civ. 99-106(JRTRLE), 2002 WL 1285089, at \*2 (D. Minn. June 5, 2002) (allegations composed of evidence that will be inadmissible at trial are properly stricken pursuant to Rule 12(f)). Further, these paragraphs violate Rule 8 as they “do not show that the plaintiff is entitled to relief...and are not an essential element of the plaintiff’s cause of action.” *Knight v. Baltimore & O.R. Co.*, 8 F.R.D. 261, 262 (W.D.N.Y. 1948). Where the plaintiff has “laid a comprehensive foundation for proving anything and everything,” such immaterial allegations must be stricken. *Eastern Fireproofing Co. v. U.S. Gypsum Co.*, 21 F.R.D. 292, 292 (D. Mass. 1958). In addition, as with paragraph 9 above, these paragraphs appear to be an appeal to the media and not to this Court and are therefore properly stricken. *McHenry*, 84 F.3d at 1177-78.

**C. Plaintiffs' Immaterial Allegations Regarding Zimmer's Sales Are Improper And Must Be Stricken**

Plaintiffs' claims relate to Zimmer's alleged activities with respect to Plaintiff's implant. Allegations regarding Zimmer's annual sales figures are immaterial, impertinent and highly prejudicial. The company's sales are irrelevant for the purpose of determining compensatory damages (the only type sought by the Plaintiffs). Therefore, pursuant to *Knight* and *U.S. ex rel. Alasker, supra*, these allegations do not belong in the complaint and must be stricken. Rule 8 provides a further rationale for striking these allegations: they violate the short and plain statement requirement and have absolutely no tendency to show that Zimmer is liable for Plaintiffs' alleged damages. The allegations of paragraph 28 are properly stricken on this basis.

**IV.  
CONCLUSION**

For the foregoing reasons, Zimmer's Motion to Strike should be granted and paragraphs 9, 17-24 and 28 should be stricken from Plaintiffs' complaint.

**V.  
REQUEST FOR ORAL ARGUMENT**

Pursuant to Local Rule 7.1(D), Defendants hereby request a hearing on their Motion to Strike.

Respectfully submitted,

Dated: February 27, 2004

Zimmer, Inc. and  
Zimmer Holdings, Inc.

By: 

Francis H. Morrison III (BBO # 645515)  
DAY, BERRY & HOWARD LLP  
CityPlace I  
Hartford, CT 06103-3499  
(860) 275-0100

Edgar B. Hatrick (BBO # 647166)  
DAY, BERRY & HOWARD LLP  
260 Franklin Street  
Boston, Massachusetts 02110  
(617) 345-4600

Matthew S. Elvin (pro hac vice)  
Dahm & Elvin LLP  
9604 Coldwater Road, Suite 201  
Fort Wayne, Indiana 46825  
Telephone: (260) 497-6000  
Facsimile: (260) 497-6019

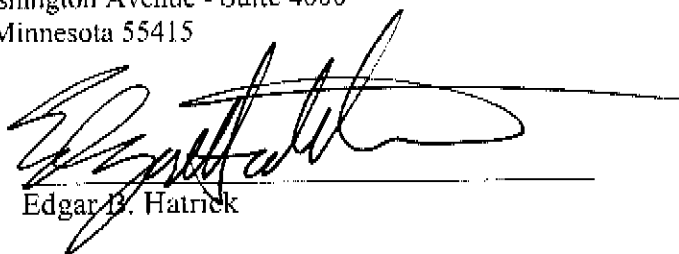
CERTIFICATE OF SERVICE

The undersigned certifies that on the 27th day of February, 2004, a copy of the foregoing Defendant Zimmer's Memorandum of Law In Support of Motion to Strike was served on the following counsel of record by first-class mail, postage prepaid:

Wm. Gerald McElroy, Jr.  
Paul T. Sullivan  
Zelle, Hofmann, Voelbel, Mason & Gette LLP  
950 Winter Street, Suite 1300  
Waltham, Massachusetts 02451

Fred H. Pritzker  
Peter H. Berge  
Elliot L. Olsen  
Pritzker Ruohonen & Associates, P.A.  
33 South Sixth Street, Suite 4520  
Minneapolis, Minnesota 55402-3792

James S. Reece  
Chad A. Snyder  
Elizabeth A. Maki  
Zelle, Hofmann, Voelbel, Mason & Gette LLP  
500 South Washington Avenue - Suite 4000  
Minneapolis, Minnesota 55415



Edgar B. Hatrick